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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,255	03/29/2001	Michael S. C. Fung	TNX 98-2-01	7231

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/821,255	FUNG ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-61* is/are pending in the application.

4a) Of the above claim(s) *58-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation-in-part of U.S. Application Serial Number 09/253,689, which claims the benefit of the filing date of provisional application 60/075,328; and also claims the benefit of the filing date of provisional application 60/191,429.

Claims 1-41 have been canceled.

New claims 42-61 have been added and are currently pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25, 2003 has been entered.

Election/Restrictions

2. Newly submitted claims 58-61 are directed to an invention that is independent or distinct from the invention originally claimed for the same reasons as set forth in Paper No. 12 with respect to claims 20-21.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **claims 58-61 are withdrawn from consideration** as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly, **claims 42-57 are the subject of examination** in the present Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 42-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has submitted new claims reciting that the antibody to Factor D "completely inhibits complement activation at a molar ratio of about 1.5:1 (antibody to Factor D)." Applicant asserts that the claims are supported in original claims 1-21 and throughout the specification. However, no such support can be found in original claims, as original claim 1 recites that at a molar ratio of 1.5:1, the inhibitor (antibody) "substantially" inhibits complement activation. The terms "substantially" and "completely" are not equivalent terms and the original claims do not provide support for the recitation of the term. In addition, adequate support for "complete" inhibition of complement activation as broadly claimed cannot be found in the specification. Applicant has not specifically pointed out where such support lies in the specification and such support has not been found by the Examiner. It is noted that Figure 26 discloses that mAb 166-32 completely inhibits the alternative complement pathway but does not affect the classical pathway (Figure 26 and page 11, lines 12-17 for example). It is further noted that Figure 18 shows that "[e]ven at a molar ratio of only 1.5:1 (MAb : factor D), MAb 166-32 can completely inhibit the alternative complement activity" as disclosed on page 59, lines 3-8, for example. No antibody disclosed in the specification is described to have the property of being able to "completely inhibit complement activation" as claimed. The term "complement activation" is readily recognized in the art as referring to both the alternative and classical pathways. However, the specification discloses only a single antibody, mAb 166-32, that is able to completely inhibit alternative complement activation at a 1.5:1 ratio and no antibodies capable of inhibiting the classical pathway at a ratio of 1.5:1. Accordingly, the recitation not only constitutes NEW MATTER, but also lacks written descriptive support in the specification for all embodiments beyond the complete inhibition of the alternative pathway by the single mAb 166-32, produced by the ATCC-deposited hybridoma HB 12476.

One of skill in the art would conclude that Applicant was not in possession of the claimed genus of anti-Factor D antibodies that completely inhibit complement activation more than at a molar ratio of 1.5:1 (antibody to Factor D). Therefore, only the monoclonal antibody disclosed as 166-32 meets the written description provision of 35 U.S.C. 112, first paragraph, FOR THE NARROWER INVENTION of completely inhibiting **alternative pathway** complement activation more than at a molar ratio of 1.5:1 (antibody to Factor D). *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the

art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention as provided by the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. Claims 42-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the monoclonal antibody 166-32, does not reasonably provide enablement for the genus of antibodies that completely inhibit complement activation at a molar ratio of 1.5:1 (antibody to Factor D). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant has submitted new claims reciting that the antibody to Factor D "completely inhibits complement activation at a molar ratio of about 1.5:1 (antibody to Factor D)." While it is noted that Figure 26 discloses that mAb 166-32 completely inhibits the alternative complement pathway but does not affect the classical pathway (Figure 26 and page 11, lines 12-17 for example) and that Figure 18 shows that "[c]ven at a molar ratio of only 1.5:1 (MAb : factor D), MAb 166-32 can completely inhibit the alternative complement activity" as disclosed on page 59, lines 3-8, for example. No antibody disclosed in the specification is described to have the property of being able to "completely inhibit complement activation" as claimed. The term "complement activation" is readily recognized in the art as referring to both the alternative and classical pathways. However, the specification discloses only a single antibody (mAb 166-32) that is able to completely inhibit alternative complement activation at a 1.5:1 ratio and no antibodies capable of inhibiting the classical pathway at a ratio of 1.5:1. given the paucity of guidance provided by the instant specification, the artisan would not be able to produce a Factor D specific antibody that is capable of completely inhibiting complement activation at a ratio of 1.5:1 (antibody to Factor D). Beyond the single species of mAb 166-32, the artisan would not be able to envision an antibody that could completely inhibit alternative pathway complement activation at a ratio of 1.5:1 (antibody to Factor D). Based upon the limited disclosure of a single species, the artisan would not be able to predict other antibodies that satisfy the metes and bounds of the claim or the conditions under which the limitations must be satisfied. It would require an undue amount of experimentation on the part of the artisan to make antibodies that satisfy the breadth of the claimed genus or to determine the conditions under which any particular antibody might satisfy the claimed limitations.

In view of the breadth of the claims, the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification,

it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

4. Claims 49-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The monoclonal antibody 166-32 recited in claims 49 and 51-57 and the antibody-producing hybridoma line HB 12476 recited in claim 50 are essential to the claimed invention. The reproduction of specific monoclonal antibodies is an extremely unpredictable event. The cell line HB 12476, disclosed at line 30 of page 2 of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the monoclonal antibody, and it is not apparent if the hybridoma producing it is readily available to the public.

It is acknowledged that Applicant's representative has affirmed that the deposit of HB 12476 has been made under the terms of the Budapest Treaty on page 4 of the paper filed April 17, 2003 in stating:

> "Applicant's representative hereby states that the deposit of HB12476 was made under the terms of the Budapest Treaty and, upon issuance of a patent from this application, all restrictions imposed upon the **depositor** will be irrevocably removed, **except the requirement to notify the patentee of a request for the deposited material**" (emphases added for clarity).

However, Applicant's representative's statement is defective for two reasons. The first is that the statement recites that restrictions upon the "depositor" will be irrevocably removed upon the issuance of a patent. This is not correct. All restrictions upon the depositor imposed by the Budapest Treaty and requirements of the USPTO will remain in force in accordance with 37 CFR 1.801-1.809. the statement should recite that all restrictions upon the "deposit" will be irrevocably removed. Second, the affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, must state that the hybridoma cell line has been deposited under the Budapest Treaty and that the hybridoma will be **irrevocably** and **without restriction or condition** released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. Applicant is not permitted to set forth exceptions in the statement that are not exactly in line with those set forth in 37 CFR 1.808. Applicant can not require the requestor to contact them directly regarding the request for deposited material. See MPEP 2410 through 2410.02.

Accordingly, Applicant should provide a new statement regarding compliance with deposit requirements.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 49 and 51-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The monoclonal antibody 166-32 is merely named in the claims by a laboratory designation which may be the same as the laboratory designation used by another to designate a completely unrelated product. Accordingly, the name "166-32" does not adequately describe the monoclonal antibody. Only designation of the antibody as a product of a deposited cell line will be sufficient to define the claimed material. Applicant should amend the claims to recite that the antibody is produced by the deposited cell line HB 12476.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
May 28, 2004

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
6/1/04